EXHIBIT A

For Opinion See 134 S.Ct. 2111 , 134 S.Ct. 1871 , 134 S.Ct. 895 , 133 S.Ct. 2879

U.S.,2014.

Supreme Court of the United States.
LIMELIGHT NETWORKS, INC., Petitioner,
v.
AKAMAI TECHNOLOGIES, INC., et al., Respondents.
No. 12-786.
April 2, 2014.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

Brief of Amicus Curiae Eli Lilly and Company, Supporting Respondents

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William L. Crowe, *The Anatomy of a Tort*, 44 Loy. L. Rev. 671 (1999) ... 22, 28

***1** INTEREST OF AMICUS CURIAE[FN1]

FN1. Pursuant to this Court's Rule 37.3(a), petitioner has provided written consent, on file with the clerk, to the filing of briefs in support of either or neither party. Respondent has provided written consent for the filing of this brief, submitted herewith. Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus* or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

Eli Lilly and Company ("Lilly") is a research-based pharmaceutical company headquartered in Indianapolis, Indiana that discovers, develops, and markets important and valuable new medicines. Lilly, together with the pharmaceutical industry as a whole, spends tens of billions of dollars annually on research and development related to bringing new medicines to the market. That research and development relates to understanding different diseases, discovering and validating potential drug targets, and discovering and developing drugs that interact with those targets to treat such diseases. It is often the case that new uses are discovered while working with known (or old) compounds. Because the compounds are known, often the only type of patent claim that will protect these particular drug products is one directed to a method of treatment.

Although this case specifically relates to the question of whether a defendant that performs some steps of a patented method and actively induces its customers to perform the remaining steps is liable for inducement of infringement under 35 U.S.C. § 271(b), the outcome will directly impact situations ***2** where the defendant does not practice any steps of the claimed method, yet actively induces others to practice the steps of the method.

The steps of method of treatment claims are sometimes unavoidably practiced by more than one entity, but often the practice of the claim is induced by a single culpable entity. Thus, it is important that the infringement laws prevent such culpable entities that stand to make significant profits at the expense of patentees from circumventing infringement liability.

SUMMARY OF THE ARGUMENT

The Federal Circuit's *en banc* decision in *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307-08 (Fed. Cir. 2012) provides the needed incentive to innovate in areas of technology where method patents are critical to capture such innovation. In areas of technology such as new treatment methods in the pharmaceutical and diagnostic industries, where it is often difficult or impossible to assert method patent claims against direct infringers, it is imperative that patentees are able to assert such claims under 35 U.S.C. § 271(b).

The *en banc* court had two choices to ensure the continued value of claims such as method of treatment claims. The court could either 1) focus solely on the culpable conduct of the "inducer," and leave the law addressing the standard for joint infringement under 35 U.S.C. § 271(a) untouched, or 2) focus on both the culpable conduct of the inducer and the entity (or entities) being induced, by requiring that there be liable direct infringers before allowing a claim of inducement and thus, overrule ***3** the agency standard required for joint infringement under 35 U.S.C. § 271(a) that has evolved since *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007).

The *en banc* majority focused on the actions of the

inducer by deciding that, regardless of whatever standard for joint infringement under section 271(a) is appropriate, that standard is irrelevant to the inquiry under section 271(b). So long as all the steps of the method are performed, and there is "active inducement" of that performance by another, who may or may not be practicing any of the method steps himself, section 271(b) liability may be found. This is the correct approach.

This approach is consistent with the policy underlying inducement law, which is to ensure effective protection for patentees when direct infringers are either not truly the culpable parties and/or are impractical to sue. Directing the inquiry to the actions of the inducer rather than to those induced, is completely in line with giving patentees a remedy when pursuing claims against direct infringers is problematic. This is precisely the case with method of treatment claims where suing doctors, pharmacists, patients, and laboratory technicians is inconsistent with the purpose of the innovation which is to help patients and actually impossible to do in the context of Hatch-Waxman litigation.

Further, the "knowledge" and "intent" requirements of induced infringement, well-developed through decisions of this Court as well as the Federal Circuit, serve the function of ensuring that only culpable conduct on the part of the accused inducer is punished regardless of whether there are ***4** culpable direct infringers. The inducer must know that acts he or she is inducing constitute acts of patent infringement (not necessarily that such actors are all themselves liable) and must take affirmative steps to bring about these acts. This standard again rightly focuses on the culpable conduct of the inducer. This is especially apropos in the context of pharmaceutical litigation where the alleged infringer is a generic company who is seeking to blatantly copy the invention and profit from the research investment of the innovator. There is no doubt the inducing party is the culpable actor.

Common law tort concepts fully support the *en banc* majority's reasoning in this case. Those concepts seek to identify an injury, assess the damage, and then compensate the victim in an attempt to make him or her whole. The Federal Circuit's decision makes it possible to do exactly that in the context of patent infringement.

A decision by this Court that there must be liable direct infringers under section 271(a) in order to pursue a claim for induced infringement under section 271(b), will require the Court to consider the appropriate standard for joint infringement under section 271(a). The "single-entity" rule, which has developed over the past several years since the *BMC* case was decided, is not the correct standard for finding joint infringement liability under section 271(a). Only a flexible approach that weighs factors that bear on the extent to which the actors are cooperating, collaborating, or conspiring to perform the steps of a method will further the policy of promoting innovation in areas of technology where method claims may be the only and best way to protect inventions. This is a policy goal that should ***5** be furthered not only by a proper interpretation of section 271(b) but the entire section 271 infringement law.

ARGUMENT

I. A Rule of Law that Requires a "Single Entity" to Directly Practice All the Steps of a Method As a Prerequisite to Finding Liability Under 35 U.S.C. § 271(b) Will Undermine Patent Protection Provided By Method of Treatment Claims.

Method of treatment claims provide necessary and valuable protection for innovation that encompasses finding new treatments and tailored therapies for important life-saving diseases. Such claims routinely involve divided infringement issues, and the patent law should support infringement actions under section 271(b).

A. The Ability to Assert Method of Treatment Claims Is a Critical Incentive for Pharmaceutical and Biotechnology Companies to Discover and Develop New Medicines.

In the pharmaceutical industry, it is commonplace for an invention to embody a new use of an old compound. Indeed, some significant advances in modern medicine have involved such ***6** innovation.[FN2] Thus, it is sometimes the case where primary patent protection comes in the form of a method of treatment claim.

FN2. Because of the common molecular origins of diverse diseases, it is estimated that approximately 90% of approved drugs possess secondary indications and can be used for other purposes. Annetine C. Gelijns et al., *Capturing the Unexpected Benefits of Medical Research*, 339 N. Engl. J. Med. 693, 695 (1998). For example: Meclazine indicated for nausea, later discovered to treat cancer; Cannabidiol indicated for nausea, later discovered to treat cancer; Perphenazine originally indicated as an antipsychotic, later discovered to treat T-cell acute lymphoblastic leukemia; Losartan originally indicated for blood pressure control, later discovered to treat breast and pancreatic cancer; and Statins originally approved as cholesterol lowering agents, recently found to show efficacy in treating colon cancer. Additionally, the following old compounds have now received FDA approval to treat various cancers: Thalidomide originally a sedative, later discovered for treatment of multiple myeloma; Celecoxib originally a pain reliever, later discovered for treatment of familial adenomatous polyposis; Methotrexate originally an anti-malarial, later discovered for treatment of osteosarcoma, breast cancer, acute lymphoblastic leukemia, and Hodgkin lymphoma; and Zoledronic acid, a bisphosphonate originally discovered to treat osteoporosis, later discovered for the treatment of metastatic bone disease.

One specific example of this from Lilly's own work involves a marketed Lilly drug known as Strattera®. Strattera® is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in both adults and children and was the very first non-stimulant ADHD medication to be marketed. Atomoxetine (the generic name of the drug) was originally discovered in the early 1970s (*see* U.S. Patent No. 4,314,081 (filed Jan. 10, 1974)) and pursued for the treatment of depression and urinary incontinence. It failed to show efficacy for ***7** those indications. *Eli Lilly and Company v. Actavis Elizabeth, LLC*, 435 Fed. App'x 917, 920 (Fed. Cir. 2011). Eventually it was discovered that atomoxetine was useful to treat ADHD, and Lilly applied for a method of treatment patent that was granted as U.S. Patent No. 5,658,590 (filed Jan. 11, 1995). By the time Lilly was ready to market the drug for ADHD, the compound patent had expired, so the only patent protection available was the method of treatment patent filed after Lilly discovered this new "use" for the drug. Ten generic drug companies initially challenged the patent under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act")[FN3] seeking to invalidate the patent. *Lilly*, 435 Fed. App'x at 917. The Federal Circuit upheld the validity of the patent and found the generic drug companies liable for induced infringement under 35 U.S.C. § 271(b). *Id.* This patent was the only protection for the necessary investment of a decade and hundreds of millions of dollars of research and development efforts to bring atomoxetine to patients. An inability to enforce such a patent would have allowed generic drugs to enter the market long before Lilly could have recouped its investment, or worse it would have foreclosed the investment in continued research on atomoxetine in the first instance, such that the successful treatment for patients would have never been discovered.

FN3. Public L. No. 98-417, 98 Stat. 1585.

Another example relates to Byetta®, which is a drug co-developed by Lilly and Amylin Pharmaceuticals.[FN4] The primary patent protection ***8** for Byetta® is also a method of treatment patent. The structure of the compound was discovered as part of the venom of the gila monster years before it was determined that it was useful to treat type 2 diabetes. *See* U.S. Patent No. 5,424,286 (filed May 24, 1993). The investment necessary to convert the compound from a component of venom to an actual medicine would never have occurred in the absence of patent protection in the form of a method of treatment.

FN4. Byetta® is now owned by Bristol-Myers Squibb

Given that it takes a significant number of years to develop a medicine for a particular use and given that the cost of such development can approach a billion dollars, it is imperative that innovators in the pharmaceutical industry be able to obtain patents that can be enforced against copiers. *See generally* Matthew Herper, *The Cost of Creating a New Drug $5 Billion Pushing Big Pharma to Change*, Forbes, Aug. 11, 2013, *http://www.forbes.com/sites/matthewherper/2013/08/11/how- the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/*. Enforceable patent rights in the form of method of treatment claims are critical to encourage the development of drugs that are not themselves patentable but that can be used to treat conditions with few or no medical options.

***9** B. Method of Treatment Claims Present Divided Infringement Issues and the Law Should Support Asserting Such Claims Against Culpable Infringers Under 35 U.S.C. § 271(b).

Method of treatment claims routinely and sometimes necessarily present divided infringement issues. For example, arguments have been made that even a simple claim directed for example to a "method of treating disease X comprising administering drug Y to a patient in need thereof," requires multiple actors to infringe the claim. This is because a physician will be required to diagnose the disease and write a prescription for a patient in need thereof, a pharmacist will fill the prescription, and a patient or another healthcare provider will administer the drug. The situation is even more complicated with combination therapy claims where more than one drug is administered to a patient or with method claims that require a doctor to determine whether a particular marker is present or absent in a biological tissue before writing a prescription or administering a drug.[FN5] Thus, for method of treatment claims it is not uncommon that ***10** to practice all the steps, a doctor, nurse, laboratory technician, pharmacist, and patient may be needed.

FN5. For example, U.S. Patent No. 8,632,983 (filed Apr. 15, 2005) is focused on methods of treating pancreatic cancer that involve taking a sample from the patient and assessing whether certain markers are present before treating; and U.S. Patent No. 8,628,920 (filed Aug. 29, 2011) is focused on treating metastatic liver cancer, and claims methods that involve assessing whether certain genes are expressed in a biological sample from the patient.

It has been increasingly common for patent challengers to argue that the relationship between these various actors does not meet the current standard articulated by the Federal Circuit necessary to find liability for direct infringement under 35 U.S.C. § 271(a). Under current Federal Circuit law, liability for infringement under section 271(a) can be found when a multiple-step process is performed by multiple actors, but only if a single actor acts as a "mastermind" who controls or directs all the other actors. *BMC*, 498 F.3d at 1378-81. Such control or direction requires more than the arm's length interactions within the health

care system.

Under the Federal Circuit's "control or direction" test as further articulated in *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), a physician and patient would likely not have the required relationship to directly infringe under section 271(a). Indeed, the now vacated panel decision in *McKesson Tech. Inc. v. Epic Sys. Corp.*, 98 U.S.P.Q.2d 1281 (Fed. Cir. 2011), which did consider section 271(a), found the doctor-patient relationship lacked the required "control or direction." The panel stated: "A doctor-patient relationship does not by itself give rise to an agency relationship or impose on patients a contractual obligation such that the voluntary actions of patients can be said to represent the vicarious actions of their doctors." *Id.* at 1284 (opinion vacated by *McKesson Tech. Inc. v. Epic Sys. Corp.*, 463 Fed. App'x 906 (Fed. Cir. 2011)). Additional actors such as other health care providers, pharmacists and laboratory technicians ***11** would also not meet the court's "control or direction" test. Although the *Akamai* and *McKesson* cases were remanded by the Federal Circuit's *en banc* decision, the "control or direction" test remains unchanged in the context of determining infringement under section 271(a). *Akamai*, 692 F.3d at 1307 ("Because the reasoning of our decision today is not predicated on the doctrine of direct infringement, we have no occasion at this time to revisit any of those principles regarding the law of divided infringement as it applies to liability for direct infringement under 35 U.S.C. § 271(a).").

Furthermore, pursuing direct infringement under 35 U.S.C. § 271(a) is generally not an option for pharmaceutical and diagnostic companies. This is not because multiple parties are needed to practice the steps of the claim, but rather because suing direct infringers would result in punishing health care providers for the appropriate practice of medicine. Thus, section 271(b) is often the only infringement provision under which pharmaceutical and diagnostic innovators can protect their inventions.

The typical case of inducement for pharmaceutical innovators arises when a generic drug company seeks approval from the FDA to sell a generic version of a patented medicine before expiry of the patents covering the medicine. This occurs when the generic company files an Abbreviated New Drug Application (ANDA) and certifies that one or more patents listed by the innovator are invalid and/or not-infringed, a so-called paragraph IV certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

The relevant statute provides that it shall be an act of infringement to submit an ANDA "if the ***12** purpose of such submission is to obtain approval … to engage in the commercial manufacture, use, or sale of a drug … claimed in a patent *or the use of which is claimed in a patent* before the expiration of such patent." 35 U.S.C. § 271(e)(2) (emphasis added). Thus, the filing of an ANDA that includes a paragraph IV certification is deemed an act of infringement, but solely for jurisdictional purposes. *See Bayer AG. v. Elan Pharm. Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Even though the filing of the ANDA is technically an act of infringement, the patentee must still prove infringement under the appropriate section of 35 U.S.C. § 271 during the ensuing lawsuit ("Hatch-Waxman Litigation"). *See, e.g., Astrazeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1056 (Fed. Cir. 2010). Litigation occurs prior to approval and launch of the generic drug product. Thus, the focus of the infringement inquiry is on the drug label as evidence of the infringement that would occur in the future if the generic drug were to be launched.

Clearly, Congress envisioned method of treatment patents to be subject to this law and to be enforced during Hatch-Waxman Litigation as evidenced by the words "or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2). Further, if a method of treatment claim is being asserted in Hatch-Waxman Litigation, necessarily only section 271(b) is available to the patentee. This is because the generic drug company is

the defendant and not physicians and patients who directly practice the steps of the method. The generic drug company generally does not directly practice any of the steps of a method of treatment claim. The focus of the ***13** infringement proceedings is thus on the generic drug label which supplies the evidence for active inducement by providing instructions to physicians or other health care providers in terms of how to use the relevant drug.

It would make little sense for the statutory language to specifically mention the "*use* of which is claimed in a patent" and then foreclose the ability to assert such patents under section 271(b) because doctors, patients, pharmacists, and potentially other health care providers were required to practice the steps of the method and such actors failed to pass the "control or direction" test as articulated in the *BMC* case.

Thus, it is imperative that the law support finding a defendant liable for induced infringement when such defendant has knowledge of a patent, and profits from actively inducing one or more actors to perform steps of a method claim in that patent such that all the steps are performed. Actors need not be in an agency relationship or contractually bound to each other but instead can have collaborative or cooperative relationships with each other such as those between doctors or other health care providers, patients, pharmacists, and laboratory technicians. Otherwise the law will act as a disincentive for pharmaceutical and biotechnology companies to work with drugs where method of treatment claims provide the primary patent protection for the drug.

***14** II. The Federal Circuit Rightly Reasoned That a Decision on Whether a Defendant Is Liable for Induced Infringement Can Be Made Without Addressing what Standard Is Necessary to Find Liability Under Section 271(a) When Multiple Actors are Required to Practice the Steps of a Method.

The Federal Circuit's decision in *Akamai* is consistent with the policy underlying inducement law, the "knowledge" and "intent" requirements associated with inducement law, and common-law tort concepts that focus on punishing the wrongdoer who has inflicted a measurable harm.

A. The Law of Induced Infringement Should Be Available When Bringing an Action Under Section 271(a) Is Not Possible.

Induced infringement is a type of secondary liability, the goal of which is to give patentees "effective protection in circumstances in which the actual infringer either is not the truly responsible party or is impractical to sue." Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 227 (2005); *See Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, LTD*, 545 U.S. 913 (2005). In addressing contributory infringement associated with a method claim directed at applying herbicide, this Court stated that the reason for the contributory infringement doctrine is to:

***15** protect patent rights from subversion by those who, without directly infringing the patent themselves, engage in acts designed to facilitate infringement by others. This protection is of particular importance in situations … where enforcement against direct infringers would be difficult, and where the technicalities of patent law make it relatively easy to profit from another's invention without risking a charge of direct infringement.

Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 188 (1980). Although in *Dawson* the Court was addressing contributory infringement, the doctrines are clearly related and both induced infringement and contributory infringement were codified based on different aspects of the law of contributory infringement that had developed prior to codification. *See* Giles S. Rich, *Infringement Under Section 271 of the Patent Act of 1952*, 21 Geo. Wash. L. Rev. 521 (April, 1953); *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2067 (2011).

Focusing on the acts and intent of the inducer rather than on the acts of those being induced is completely consistent with the goal of giving patentees a remedy when pursuing claims against direct infringers is difficult. As mentioned above, method of treatment claims are difficult, if not impossible within Hatch-Waxman Litigation, to assert against direct infringers. The Federal Circuit's decision makes it possible to assert such claims when assertion under section 271(a) is unavailable to the patentee.

***16** Another specific provision of the Patent Act that only makes sense if section 271(b) is interpreted to further the policy goal of providing an avenue to pursue infringement claims when section 271(a) is unavailable is the "Physician's Immunity Statute." 35 U.S.C. § 287(c). This is a specific provision of the patent law that grants immunity from patent infringement to "medical practitioners" and "related health care entities" when they engage in medical and surgical procedures performed on the body.[FN6] *Id.* This section was enacted to alleviate concerns expressed by the American Medical Association, that without the statute, doctors would not have the freedom to perform life-saving surgical procedures, doctors would be unable to provide adequate patient care, health-care costs would increase for patients, and patient confidentiality could be compromised when doctors and hospitals were sued for patent infringement.

> FN6. Note that a medical practitioner or health-related entity using a drug for a patented "use" would not be immunized from liability under any sub-section of 35 U.S.C. § 271.

Thus, to avoid section 287(c) making patents covering medical and surgical procedures performed by medical practitioners completely worthless, section 271(b) must be available to assert against indirect infringers. For example, a surgical device company that patents the use of a device to perform a surgical method has no recourse under section 271(a). However, if a competitor device company attempted to sell the device with instructions on how to use it by practicing the patented method, section 271(b) should be available to the patentee. By ***17** enacting section 287(c), Congress underscored the important policy of allowing an action under section 271(b) when claims under section 271(a) are not available.

B. The "Knowledge" and "Intent" Requirements Properly Limit the Scope of Induced Infringement Even If Proving Liability Under Section 271(a) Is Not a Prerequisite.

The "knowledge" and "intent" requirements associated with proving infringement under section 271(b) should alleviate any concerns that might arise as a consequence of eliminating the inquiry into whether there is direct infringement liability associated with the inducer's actions. *Contra Akamai*, 692 F.3d at 1333 (Newman, J., dissenting).

In *Grokster*, this Court addressed induced infringement in the copyright context by referencing the patent law related to induced infringement. 545 U.S. at 935. Concerned about the impact on innovation of a new "inducement" rule in the copyright context, this Court stated that:

mere knowledge of infringing potential or of actual infringing uses would not be enough here to subject the distributor to liability.… The inducement rule, instead, premises liability on purposeful, culpable expression and conduct, and thus does nothing to compromise legitimate commerce or discourage innovation having a lawful purpose.

***18** *Id.* at 937.

The substantive standards as set out by this Court and by the Federal Circuit for an inducement claim require

that the patentee establish that there has been direct infringement, and that the defendant knowingly induced such infringement and possessed specific intent to encourage that infringement. *ACCO Brands, Inc. v. ABA Locks Mfr. Co.*, 501 F.3d 1307, 1312 (Fed. Cir. 2007). There is no argument that the acts that constitute direct infringement need not be present in fact or in the legal construct of Hatch-Waxman Litigation. Rather, the argument focuses on whether the patentee must prove that the entity or entities being induced are themselves liable for direct infringement.

This Court has stated that "inducement must involve the taking of affirmative steps to bring about the desired result." *Global-Tech.*, 131 S. Ct. at 2065. In *Global-Tech*, this Court addressed the issue of whether knowledge of the patent is needed for induced infringement. *Id.* The Court concluded that "induced infringement under 35 U.S.C. § 271(b) requires knowledge that the induced acts constitute patent infringement." *Id.* at 2068. The Court determined that "willful blindness" would also suffice to meet the knowledge requirement. *Id.* at 2069.

The "knowledge" requirement is important because it focuses on whether the inducer knows that acts he or she is inducing constitute acts of patent infringement. A potential inducer may be unaware whether and how multiple parties have contracted with each other to perform the steps of a particular method. For example, a generic drug ***19** manufacturer may not know whether a one step or two step method claim of diagnosing and treating is carried out only by the attending physician, or by the nurse practitioner, or other qualified health care staff; and as a matter of law it should not matter. Merely understanding and knowing that one's active conduct results in one or more parties performing every element of a patent claim (or being willfully blind thereto) suggests intentional, culpable conduct and thus, should suffice.

The knowledge and specific intent requirements associated with section 271(b) make it clear that inducement requires evidence of culpable conduct directed to actively encouraging infringement by others in a way that benefits the inducer and harms the patentee. *See DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc). That culpable conduct is present regardless of whether the direct infringement that is being induced results in liability to all, some, or none of the direct infringers. The harm to the patentee still occurs with a resultant benefit to the inducer.

Further, in the context of the Federal Circuit's *en banc* decision in *Akamai*, the court's holding in no way expands the rules governing direct infringement. The court simply did not address the applicable standard under section 271(a). Holding that an "inducer" can be liable for infringement without examining "liability" for direct infringement in no way suggests that all the direct infringers are innocent.

Judge Newman suggests in dissent that with the "new 'inducement only rule,' the inducing entity is liable on greatly enlarged grounds, such as merely advising or encouraging acts that may constitute ***20** direct infringement." *Akamai*, 692 F.3d at 1319. However, if knowingly advising or encouraging actually causes performance of all claim steps, regardless of whether by one or more entities, and there is damage to the patentee with a resultant benefit to the inducer, liability under section 271(b) is perfectly reasonable.

The law from this Court and the Federal Circuit is well developed in the context of determining when the "knowledge" and "intent" elements are met and such law properly focuses the issue on whether the potential inducer has committed culpable conduct resulting in an injury to the patentee.[FN7] *See DSU*, 471 F.3d at 1306.

FN7. While not controlling, other jurisdictions have found liability for inducing infringement analogously to section 271(b).

> For example, Lord Justice Jacob and Etherton expressed the U.K. test for indirect infringement in paragraph 131 of a leading case as follows: "In short, the knowledge and intention requirements of Art. 26 and section 60(2) are satisfied if, at the time of supply or offer of supply, the supplier knows, or it is obvious in the circumstances, that ultimate users will intend to put the invention into effect. *Grimme Maschinenfabrik GmbH & Co KG v. Derek Scott* [2010] EWCA Civ 1110, [2011] 7 FSR 224. The declared purpose of the agreement on Trade-Related Intellectual Property Rights (TRIPS) is harmonization of patent laws, including infringement. *Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1253 (Fed. Cir. 2000).

***21** C. The Federal Circuit's Decision Is Consistent with Common-law Tort Concepts that Focus on Punishing the Wrong-doer.

This Court has recognized that secondary liability (e.g., indirect infringement in the copyright context) is based on well-established principles of common law. *Grokster*, 545 U.S. at 930. In distinguishing the *Sony* case, the *Grokster* Court noted that "nothing in *Sony* requires courts to ignore evidence of intent if there is such evidence, and the case was never meant to foreclose rules of fault-based liability derived from the common law." *Id.* at 934-935; *see Sony Corp. v. Universal City Studios*, 464 U.S. 417 (1984). In addition, the Court reasoned,

> [t]he classic case of direct evidence of unlawful purpose occurs when one induces commission of infringement by another, or "entice[es] or persuad[es] another" to infringe, Black's Law Dictionary 790 (8th ed. 2004), as by advertising. Thus, at common law a copyright or patent defendant who "not only expected but invoked [infringing use] by advertisement" was liable for infringement *"on principles recognized in every part of the law."*

Grokster, 545 U.S. at 935 (alterations in original, citations omitted, emphasis added).

The common law of torts seeks to "place a value upon harms so that, theoretically, the plaintiff can be made whole again" and such an evaluation constitutes an assessment of the plaintiff's injury. ***22** William L. Crowe, *The Anatomy of a Tort*, 44 Loy. L. Rev. 671 (1999). In the context of method claims generally, one who actively induces others to do one or more acts and causes an injury to the patentee as a result of that inducement should be liable and required to make the patentee whole.

In *Grokster*, even though there were clearly direct infringers, the court adopted the theory of induced infringement (not previously part of copyright law) because of the magnitude of the harm inflicted through the use of defendants' software. 545 U.S. at 929. The Court also noted that "a further complement to the direct evidence of unlawful objective" was that defendants made money "by selling advertising space, by directing ads to the screens of computers employing their software.… [T]he more the software is used, the more ads are sent out and the greater the advertising revenue becomes." *Id.* at 939-40.

The Federal Circuit's opinion in this case properly focused on who was profiting at the expense of whom regardless of what liability rules might exist for any underlying direct infringement. A consideration of method of treatment claims similarly underscores the need to properly focus on the actions of the inducer and resultant harm to the patentee when examining rules of inducement liability. For example, in the context of a Hatch-Waxman Litigation, if a generic drug company is free to market its generic drug for a patented method of treatment, the innovator patentee stands to lose potentially millions of dollars overnight once the generic drug is launched. The generic company, on the other hand, by relying completely on the work of the innovator, stands to make a substantial profit.

***23** Courts have maintained a flexible approach when fashioning different theories of liability to make sure that those who inflict harm are held responsible. *See, e.g., In re Methyl Tertiary Butyl Ether Prod. Liab. Litig.*, 379 F. Supp. 2d 348, 375 (S.D.N.Y. 2005) (expanding alternative liability rather than rigidly apply traditional tort principles to ensure responsible parties were punished). Further, when applying theories of liability, courts appear to err on the side of holding parties liable rather than letting everyone go free merely because liability might be difficult to assess. *Id.*

[F]rom time to time courts have fashioned new approaches in order to permit plaintiffs to pursue a recovery when the facts and circumstances of their actions raised unforeseen barriers to relief. Those courts made a policy decision that in balancing the rights of all parties, it would be inappropriate to foreclose plaintiffs entirely from seeking relief merely because their actions did not fit the parameters of existing liability theories.

Id. at 377.

It is not generally difficult to apply the "knowledge" and "intent" requirements and determine whether an accused inducer is liable for infringement under section 271(b). The Federal Circuit's approach to induced infringement properly focuses the issue on the actions of the wrong-doer (e.g., the party inducing the infringing acts).

***24** III. If Actionable Direct Infringement Must Be Found Under Section 271(a) Before Allowing a Claim for Induced Infringement Under Section 271(b), the Federal Circuit's "Single Entity" Rule Must Be Abandoned.

If the Court finds it necessary to address section 271(a) liability, it should apply a standard that encompasses actors that are collaborating or acting in concert. The statutory language of 35 U.S.C. § 271(a) does not support a restrictive "single-entity" rule. "Whoever," as used in section 271(a), is not limited to single entities and includes multiple actors. Such usage is consistent with contemporaneous dictionary definitions and the United States Code which specifically notes that the word "whoever" includes "corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." 1 U.S.C. § 1. Further, it is unclear what else Congress could do to clarify the language except to say that "whoever" really means the plural (which 1 U.S.C. § 1 already says).

As noted above, the Federal Circuit did not address the standard of direct infringement for multiple actors under section 271(a) in its *en banc* decision. *Akamai*, 692 F.3d at 1307. In addition, even though the *en banc* court overruled the *BMC* decision, it did so only in the context of that court holding that in order for a party to be liable for induced infringement "some other single entity must be liable for direct infringement." *Id.* at 1306. Thus, the *en banc* court did not directly overrule any ***25** precedent dealing with the standard for joint infringement under 35 U.S.C. § 271(a).

Thus, the lineage of cases starting with *BMC* make it clear that the Federal Circuit has adopted a high standard of "control or direction" by analogy to the law of agency. The Federal Circuit described the standard as follows:

Although the control or direction standard is satisfied where the accused direct infringer is vicariously liable for the actions of a third party who completes performance of the claimed method, that does not describe the situation here. The terms of the MOU do not contain any express or implicit agreement that TSA will act on Travel Sentry's behalf or subject to its control, as an agency relationship would require. *See Dixon v. United States*, 465 U.S. 482, 505 (1984) ("[An] agency relationship [is] created when one person agrees with another 'that the other shall act on his behalf and subject to his control.' " (quoting Re-

statement (Second) of Agency § 1 (1957)).

Travel Sentry, Inc. v. Tropp, 497 Fed. App'x 958, 966 (Fed. Cir. 2012) (alterations in original). The court further clarified the standard in *Aristocrat Tech. Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348 (Fed. Cir. 2013):

One party's direction or control over another in a principal-agent relationship or like contractual relationship operates as an exception to this general rule, but absent that ***26** agency relationship or joint enterprise, we have declined to find one party vicariously liable for another's actions. IGT has no such relationship with the player. Neither is the agent of the other, nor can we discern a theory under which one would be vicariously liable for the other's actions.

Id. at 1363 (citations omitted).

The Federal Circuit, in its *en banc* opinion, recognized that setting such a high standard under which multiple actors may be liable for joint infringement under section 271(a) may allow collaborative infringement to go unpunished:

Absent an agency relationship between the actors or some equivalent, however, a party that does not commit all the acts necessary to constitute infringement has not been held liable for direct infringement *even if the parties have arranged to "divide" their acts of infringing conduct for the specific purpose of avoiding infringement liability.*

Akamai, 692 F.3d at 1307 (emphasis added). However, setting a standard of "control or direction" that condones subverting the patent laws to allow an infringer to strip an inventor of the benefits of a process or method patent claim by orchestrating claim steps to be conducted by others undermines an entire class of patents that is not limited to high tech computer systems. This simply cannot be the law.

Further, the analogy to the law of agency is misplaced and inconsistent with the common law origins of infringement liability in tort. The Federal ***27** Circuit's application of a "single-entity" rule must be rejected, and the standard for finding multiple actors to be infringers under section 271(a) should be analogous to the standard for joint tortfeasors. Thus, joint actors acting in concert, pursuant to a common design or plan[FN8], or the "mastermind" who directs other independent actors (who may fall well short of acting as legal agents of the mastermind) should be liable for infringement under 271(a).

FN8. 74 Am. Jur. 2d *Torts* § 68

The "single-entity" rule evolved, in part, due to concerns about expanding the rules of liability such that so-called "innocent infringers" would be ensnared. *BMC*, 498 F.3d at 1381. In *BMC*, the court was concerned about a party trying to avoid infringement "simply by contracting out steps of a patented process to another entity." *Id.* In addition, the court recognized that this "control" requirement would still allow parties to enter into arms-length agreements to avoid infringement, but reasoned that this concern does not outweigh "concerns over expanding the rules governing direct infringement." *Id.*

The court, however, was too short sighted and failed to properly balance the concerns. The court's "single-entity" standard immunizes from joint infringement all other forms of cooperation, collaboration, and conspiracy available to would-be infringers. Further, if such a rule controls not only direct infringement under section 271(a), but also indirect infringement under section 271(b), then the rule does not provide the proper incentive to innovators such as pharmaceutical and diagnostic ***28** companies to pursue medicines or diagnostics to address unmet medical needs. Surely this incentive should outweigh any hypothetical concerns invoked to argue for contraction of the rule governing direct infringement. The incentive to innovate should also prevail as it reflects the Constitutional mandate underlying the patent sys-

tem.[FN9]

FN9. "To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8

Further, as noted above, courts have been extremely creative in fashioning rules of liability to ensure consistency with one of the cardinal rules of tort law: "the 'badder' you are, the more likely you are to be held liable for more extensive harms and in greater amounts." Crowe, *supra* at 679. Over the past several decades, it does not appear that courts have had difficulty in analyzing joint infringement issues where multiple parties are practicing different steps of a method claim. There are a number of district court cases that applied a flexible approach in considering the issue of divided infringement prior to the Federal Circuit's establishment of the "single-entity" rule in the *BMC* case. *See, e.g., Mobil Oil Corp. v. W.R. Grace & Co.*, 367 F. Supp. 207, 253 (D. Conn. 1973) (defendant liable for direct infringement under section 271(a) despite not performing every element of the asserted patent claims itself, because it knew that its customers would perform the remaining steps); *Shields v. Halliburton Co.*, 493 F. Supp. 1376, 1389 (W.D. La. 1980) (method claims were singularly and jointly infringed by defendants where one had instructed the other to perform an ***29** infringing step); *Cordis Corp. v. Medtronic Ave, Inc.*, 194 F. Supp. 2d 323, 349 (D. Del. 2002) (stating that "if two or more entities perform different steps of the method, those entities must have some connection to each other"); *Hill v. Amazon.com, Inc.*, No. 02-CV186, 2006 WL 151911, at *2 (E.D. Tex. Jan. 19, 2006) (stating that "a showing of 'agency' or 'working in concert' is not necessarily required" so long as there is some direction exchanged by the parties). The approach these courts have taken is sensible and furthers the policy goal of preventing actors from avoiding liability by instructing another to perform a final (or other) step of a patented method.

Dominant themes in recent Supreme Court intellectual property jurisprudence, are aversion to hard-and-fast rules and a demand for flexible legal doctrine. *See eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). Such an approach allows courts to adapt to technological development and changed circumstances. While method claims are not new, the multitude of divided infringement issues associated with such claims is a fairly recent phenomenon. *See* Hayden W. Gregory, *Proving Infringement in Divided Performance Process Claims: Something's Gotta Give*, 5 Landslide 1 (2012); Keith Jaasma, *Finding the Patent Infringement "Mastermind": The "Control or Direction" Standard for Joint Infringement*, 26 Santa Clara Computer & High Tech. L.J. 411, 429 (2010) (finding that "the rate at which district courts have decided issues related to 'joint' or 'divided' infringement has increased significantly" in recent years); Stacie L. Greskowiak, ***30***Joint Infringement after BMC: The Demise of Process Patents*, 41 Loy. U. Chi. L.J. 351, 402 (2010) (noting that the use "of multiple entities to carry out a process" is common in "the technology, communication, and medical industries"). Thus, if the Court deems it appropriate to address section 271(a) liability in the context of joint infringement, the Court should consider a flexible approach that weighs factors that bear on the extent to which the parties are acting at the direction of a single mastermind, cooperating, collaborating, or conspiring to perform the steps of the method, rather than apply a rigid "single-entity" rule.

CONCLUSION

Permitting the "gaming" of the patent system by a culpable infringer with an overly strict and rigid interpretation of sections 271(a) and/or 271(b) will be a disincentive to companies doing research and devel-

opment in a number of technology areas. Clearly, a rigid interpretation would create this disincentive in the pharmaceutical industry where method of treatment claims provide critical protection for new uses of medicines to treat lifesaving diseases. This Court, either by affirming the Federal Circuit's application of 271(b), or by finding infringement under 271(a) when multiple parties act in concert or at the direction of a mastermind to complete the steps of a patent claim, will promote the progress of research and development and prevent subversion of the patent system by culpable entities.

Limelight Networks, Inc. v. Akamai Technologies, Inc.
2014 WL 1319146 (U.S.) (Appellate Brief)

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